



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

February 14, 2002

MEMORANDUM

Subject: Efficacy Review for T.B. Phene, EPA Reg. No. 211-36.
DP Barcode: D

From: Michele E. Wingfield, Chief
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Thru: Michael Hardy, Coordinator
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Producer: Central Solutions
POB 15276
3130 Brinkerhoff Road
Kansas City, Kansas 66115

Formulation From Label:

Active Ingredient(s)

% by

	<u>wt</u>
Sodium ortho-benzyl-para-chlorophenate.	4.40
Sodium ortho-phenylphenate	2.82
Sodium para-tertiary-amylphenate	2.49

I. BACKGROUND

The submitted studies, received November 20, 2001, were conducted at the Office of Pesticide Program's Microbiology Laboratory as part of the Antimicrobial Testing Program. On July 12, 2001, the laboratory received three samples of the product. Sample number 071201F257401-1 (lot no. 04041007), 071201F257401-4 (lot no. 06281002), and 071201F257401-7 (lot no. 1228007) were tested using the AOAC Use-Dilution Test against *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

II. USE DIRECTIONS

Directions for Cleaning and Disinfection: For broad spectrum disinfection of gram negative and gram positive bacteria, including *Pseudomonas aeruginosa*, add 1 ounce T.B. Phene to one gallon of water. Remove heavy soil or gross filth then apply solution with a mop, cloth, sponge, or hand pump trigger sprayer, so as to wet the surface thoroughly. Allow to remain wet for 10 minutes and then let air dry.

III. AGENCY STANDARD FOR DISINFECTANTS HOSPITAL OR MEDICAL ENVIRONMENT

Test requirements. **Disinfectants (hospital or medical environment efficacy).** When a product is recommended in labeling for use in hospitals, clinics, dental offices, nursing homes, sickrooms, or any other medical-related facility, the following requirements apply: Sixty carriers for each of three samples, representing three different batches, one of which is at least 60 days old, must be tested against each of the following: *Salmonella choleraesuis* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442).

Performance standard. The product must kill the test microorganisms on 59 out of each set of 60 carriers/slides to provide significance at the 95 percent confidence level.

IV. BRIEF DESCRIPTION OF THE DATA

Testing of the three samples of the product was conducted on August 14, 2001, against *Staphylococcus aureus*, and on August 15, 2001 against *Pseudomonas aeruginosa*. The method used was the AOAC Use-Dilution Test with the following modifications: The product was diluted 1:128 in sterile deionized water. The carrier count was 3.1×10^6 CFU/carrier for *S. aureus* and 7.1×10^6 for *P. aeruginosa*. 5% horse serum was added to the inoculum as a soil load. Testing was conducted at a contact time of 10 minutes at room temperature. Lethen broth was used as the neutralizer and subculture medium. The treated carriers were incubated

for 48±2 hours at 37°C.

V. RESULTS

Sample Number	Lot Number	Organism	Number +/- Number Tested
071201F257401-1	04041007	<i>Staphylococcus aureus</i>	1/60 (contaminant)
		<i>Pseudomonas aeruginosa</i>	1/60
071201F257401-4	06281002	<i>Staphylococcus aureus</i>	2/60
		<i>Pseudomonas aeruginosa</i>	1/60 (contaminant)
071201F257401-7	1228007	<i>Staphylococcus aureus</i>	0/60
		<i>Pseudomonas aeruginosa</i>	0/60

VI. CONCLUSIONS

The submitted data supports the effectiveness of two batches of the product, T.B. Phene (EPA Reg. No. 211-36) as a hospital disinfectant when tested against *Staphylococcus aureus* and *Pseudomonas aeruginosa* by the AOAC Use-Dilution Test for a 10 minute contact time at room temperature. One batch (071201F257401-4, lot no. 06281002) failed to show effectiveness against *Staphylococcus aureus*.

VII. RECOMMENDATIONS

The one batch that failed against *Staphylococcus aureus* should be removed from the marketplace.